

B9 coating tenacity and bioactivity sufficient to permit the coating to substantially prevent endoleaking when deployed and used *in vivo*.

20. An endovascular graft prepared by the method of claim 11.

B10 21. A method of preventing endoleaking in the course of deploying and using an endovascular graft that comprises an expandable stent portion and a stent cover, the method comprising the step of first coating the stent cover in the manner of claim 11.

#### Remarks

The specification has been amended to respond to the Examiner's objection relating to incorporation by reference. Suitable non-photoreactive methods of coating the material will be well known to those skilled in the art, given the present description, and the reference used is merely exemplary.

Claims 1-7, 9-17 and 19-21 were pending. Claims 2,4,12, and 14 have been cancelled, and claims 1,3,5,7,9-11,13,15-17, and 19-21 have been amended in order to place them in better condition for allowance, or in the alternative, for consideration on appeal. Upon entry of the amendment, claims 1,3,5-7,9-11,13,15-17, and 19-21 will be pending and in condition for allowance. The amendment raises no new issues, nor would it entail the need for further search on the part of the Examiner. Entry of the amendment is within the discretion of the Examiner and is respectfully requested.

The Examiner rejected claims 2-5, 7,9, 12-15, 19, and 21 under §112. These rejections have been overcome through amendment of the claims. Specifically, the modifying phrase in claims 7 and 17 has been clarified, and both claims 2 and 12 have been cancelled, in addition to editorial amendments to claims 3,9,10,15, and 19 responsive to the Examiner's detailed comments in the office action mailed May 24, 2002.

The Examiner rejected claims 1-3, 6-7, 9, 11-14, 16-17, and 19-21 as anticipated according to §102(e) by Turnlund et al. (6,296,603 B1). This rejection has been overcome through requested amendment of the claims. The Examiner has stated that "Turnlund et al. discloses an endovascular graft that is coated with collagen however fails to disclose how the collagen is adhered to the graft." This, in turn, appears to be the reason that claim 4 was not rejected under §102(e). In view of this, the limitation provided by claim 4; namely, "covalently attached in the form of a thin, conformal coating" has now been added to both independent claims 1 and 11. As these claims are no longer anticipated by Turnlund et al, they should be in condition for allowance.

The Examiner rejected claims 4-5, 10, and 15 as being unpatentable according to §103 over Turnlund et al. (6,296,603 B1) in view of Clapper (5,744,515). Turnlund et al. is

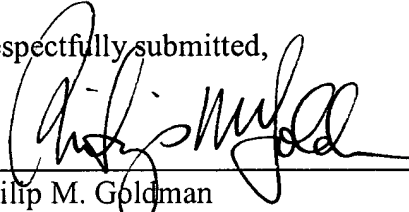
distinguished for the reasons provided above, and for others as well, and Clapper does nothing to remedy these defects. The combination of Clapper's use of photoreactive groups with Turnlund's radioactive endovascular prosthesis is submitted to be improper because neither Clapper nor Turnlund suggest such a combination, and one skilled in the art would have no reason to make such a combination. Moreover, since the present invention is intended to promote interaction with the surrounding tissue, Clapper teaches away from this by describing a device with reduced interaction with surrounding tissues.

Accordingly, entry of the present Amendment and reconsideration of the pending rejection is respectfully requested. The Examiner is encouraged to telephone the undersigned in the event any remaining issues arise.

The Commissioner is hereby authorized to charge any additional filing fees required to Deposit Account No. 061910. A duplicate copy of this sheet is enclosed.

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Respectfully submitted,



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## VERSION WITH MARKINGS TO SHOW CHANGES MADE

Amendments to the specification (where insertions are underlined and deletions placed in brackets):

Please amend the paragraph beginning on page 15, line 17 as shown:

The coating can be applied at the time of manufacture of the material itself, in the course of its fabrication into a endovascular graft cover, and/or at the time of use. Suitable non-photoreactive methods for coating such materials (in either a covalent or noncovalent fashion) are described in Hoffman, A.S., "Immobilization of Biomolecules and Cells on and within Polymeric Biomaterials", *Clin. Mat.* 11:61-66 (1992)[, the disclosure of which is incorporated herein by reference].

Amendments to the claims (where insertions are underlined and deletions placed in brackets):

1. (once amended) An endovascular graft comprising an expandable stent portion and a stent cover portion, wherein the stent cover portion is coated on at least the outer surface with a bioactive agent covalently attached in the form of a thin, conformal coating in a manner sufficient to promote initial thrombus formation.

3. (once amended) A graft according to claim [2]1 wherein the stent cover portion is prepared from a porous material selected from PET and ePTFE and the bioactive agent comprises collagen.

5. (once amended) A graft according to claim [4]1 wherein the agent is attached by the activation of photoreactive groups provided by the stent cover portion[material], by the bioactive agent, and/or by a linking agent.

7. (once amended) A graft according to claim 6 wherein the agent comprises a protein or the active portions and domains of a protein selected from the group consisting of collagen, thrombin, fibrinogen, elastin and von Willebrand factor[, including active portions and domains thereof].

9. (twice amended) A graft according to claim [2]<sub>1</sub> wherein the agent is attached to the stent cover portion in a manner that provides a) a minimal increase in overall bulk, sufficient to permit the graft to be deployed in a minimally invasive fashion, and b) a combination of coating density, coating tenacity and bioactivity sufficient to permit the coating to substantially prevent endoleaking when deployed and used *in vivo*.

10. (twice amended) An endovascular graft comprising an expandable stent portion and a porous stent cover portion selected from PET and ePTFE, the porous stent cover portion being coated with a bioactive agent comprising collagen, wherein the collagen is covalently attached in a thin, conformal coating to the porous stent cover portion in a manner sufficient to promote initial thrombus formation followed by long term fibrous tissue ingrowth, and wherein the coating is covalently attached by the activation of photoreactive groups provided by the porous stent cover portion, by the bioactive agent, and/or by a linking agent.

11. (once amended) A method of preparing an endovascular graft comprising an expandable stent portion and a stent cover portion, comprising the steps of coating [an endovascular graft with a bioactive agent] at least the outer surface of the stent cover portion with a bioactive agent that is covalently attached in the form of a thin, conformal coating in a manner sufficient to promote initial thrombus formation.

13. (once amended) A method according to claim [12]11 wherein the stent cover portion is prepared from a porous material selected from PET and ePTFE and the bioactive agent comprises collagen.

15. (once amended) A method according to claim [14]11 wherein the agent is attached by the activation of photoreactive groups provided by the stent cover portion[material], by the bioactive agent, and/or by a linking agent.

17. (once amended) A method according to claim 16 wherein the agent comprises a protein or the active portions and domains of a protein selected from the group consisting of collagen, thrombin, fibrinogen, elastin, and von Willebrand factor[, including active portions and domains thereof].

19. (twice amended) A method according to claim [12]11 wherein the agent is attached to the stent cover portion in a manner that provides a) a minimal increase in overall bulk, sufficient to permit the graft to be deployed in a minimally invasive fashion, and b) a combination of coating density, coating tenacity and bioactivity sufficient to permit the coating to substantially prevent endoleaking when deployed and used *in vivo*.

21. (once amended) A method of preventing endoleaking in the course of deploying and using an endovascular graft that comprises an expandable stent portion and a stent cover, the method comprising the step of first coating the stent cover in the manner of claim 11[12].

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